Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Solian 400 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 400 mg amisulpride.

Excipient with known effect
Lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from Greece
Oblong,white scored tablet engraved "AMI 400" on one side of it.
The score line is only to faciliate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA0540/158/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/158/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Sodium carboxymethyl starch
Lactose monohydrate
Cellulose, microcrystalline
Hypromellose
Magnesium stearate

Coating
Hypromellose
Cellulose, microcrystalline
Polyoxyl 40 stearate
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

Blisters of 60 film-coated tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkenweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/019/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd August 2019

10 DATE OF REVISION OF THE TEXT